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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/480, 977	01/11/00	GODOWSKI	P P1084R1C1

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EXAMINER

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HUNT, J

ART UNIT	PAPER NUMBER
1642	4

DATE MAILED:

12/11/00

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	Application No. 09/480,977	Applicant(s) Godowski et al.
	Examiner Jennifer Nichols, Nee Hunt	Group Art Unit 1642

Responsive to communication(s) filed on \_\_\_\_\_.

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 1 and 4 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 1 and 4 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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**DETAILED ACTION**

1. Acknowledgment is made of the cancellation of claims 2, 3, and 5-38. An action on the merits of claims 1 and 4 follows.

***Claim Rejections - 35 USC § 112***

2. Claims 1 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 4 are indefinite in the recitation of "the EDGF-like domain of SEQ ID NO:4". The recitation lacks antecedent basis, and further the metes and bounds cannot be determined. It is not clear what would be considered an EDGF-like domain and what would not, further, it is not clear if the EDGF-like domain can constitute a part of SEQ ID NO:4, or if it must include all of SEQ ID NO:4, or if SEQ ID NO:4 is just a part of the domain.

3. Claims 1 and 4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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Factors to be considered in determining scope and enablement are: 1) quantity of experimentation necessary, 2) the amount of direction or guidance presented in the specification, 3) the presence or absence of working examples, 4) the nature of the invention, 5) the state of the prior art, 6) the relative skill of those in the art, 7) the predictability of the unpredictability of the art, and 8) the breadth of the claims (see *Ex parte Forman*, 230 USPQ 546, BPAI, 1986).

The claims are broadly drawn to an isolate polypeptide comprising an EDGF -like domain of SEQ ID NO:4. As set forth above, the metes and bounds of said EDGF-like domain cannot be determined. Thus in light of the broad scope of the instant claims, which appear to include any and all polypeptides which contain certain portions of SEQ ID NO:4 and variants thereof, absent clarification to the contrary, the disclosure of a single EGDF-like domain which activates tyrosine phosphorylation is insufficient support under U.S.C. 112 first paragraph to enable claims broadly drawn to any and all EDGF-like domain containing polypeptides. The specification provides no objective evidence that any and all polypeptides encoding the EDGF-like domain of SEQ ID NO: 4 would function as the single taught EDGF-like polypeptide does, to activate tyrosine phosphorylation of the ErbB4 receptor. The disclosure of one polypeptide is insufficient support under the first paragraph of 35 U.S.C 112 for claims which encompass any and all polypeptides comprising SEQ ID NO:4, including those yet undiscovered. The courts have held that:

“Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since some

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improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and hence, not in compliance with the first paragraph of U.S.C. 112; that paragraph requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved." In re Fisher 427 F.2d 833, 166 USPQ 18 (CCPA 1970)

Furthermore, the amount of embodiments corresponding to the desired function may be innumerable and include receptor inhibitors which are yet undiscovered, while the current embodiments amount to only one. Reasonable correlation must exist between the scope of the enablement set forth and the scope of the claimed subject matter. Therefore one of ordinary skill in the art would not be enabled to practice the invention commensurate with the scope of the claims.

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4. Claims 1 and 4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claims are broadly drawn to an EDGF-like domain containing polypeptide of any size comprising a sequence all or part of SEQ ID NO:4. The claims are drawn to a peptide of any size which is only defined by a small number of amino acid residues, hence the claims are drawn to amino acid residues which minimally contain only portions of SEQ ID NO:4. Thus the claims are drawn to a large genus of molecules. In the case of small identified amino acid residues claimed with open language, the genus of the polypeptides comprising a partial sequence encompasses a variety of subgenera with widely varying attributes. The specification discloses only the structural features of one species of EDGF-like domains. The specification lacks information to lead one of ordinary skill in the art to understand that the applicant had possession of the broadly claimed genus of polypeptides at the time the instant application was filed.

Applicant is referred to the interim guidelines 112, first paragraph, published in the Official gazette and also available on [www.uspto.gov](http://www.uspto.gov).

No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Nichols, whose telephone number is (703) 308-7548. The examiner can normally be reached Monday through Thursday 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached at (703) 308-3995. The fax number for the group is (703) 305-3014 or (703) 308-4242.

Communications via internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [\[anthony.caputa@uspto.gov\]](mailto:[anthony.caputa@uspto.gov]).

All internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists the possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist, whose telephone number is (703) 308-0196.

Jennifer Nichols, Nee Hunt

December 4, 2000

  
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